United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: ● Original 1-58 ○ Amendment

Contract Number: EP-C-09-027 | Contract Period: 04/01/2010 - 03/31/2011 | Option Period No. 1 | SF Site Name:

Title of Work Assignment: The Impact of Decontamination Technologies (Ethylene Oxide) on Materials and Equipment

Suggested Source: Arcadis | Specify Section & Paragraph of Contract SOW:

Purpose: ● Work Assignment Initiation ○ Work Assignment Close-Out ○ Work Assignment Amendment ○ Incremental Funding ○ Work Plan Approval

Period of Performance From: To: 03/31/2010

Comments: See attached SOW

CA Category (check one)
○ I Enforcement
○ II Standard Setting
○ III Technology Development
● IV Proof of Concept
○ N/A

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO 22 (Max 2) Superfund ○ Non-Superfund

Accounting and Appropriations Data

	DCN (Max 6)	Budget/FYs (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount	Sites/Project (Max 8)	Cost Org/Code (Max 7)
1									
2									
3									
4									
5									

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee	LOE
Previously Approved	New	0
This Action		0
Total		0

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: Shannon Serre 9/12/10 (Signature) (Date)	Branch / Mail Code: NHSRC / E343-06 Phone Number: (919) 541-3817 Fax Number:
Branch Chief Name: Shawn Ryan - Director, DCMD (Signature) (Date)	Branch/Mail Code: NHSRC / E343-06 Phone Number: Fax Number:
Project Officer Name: Diane Pierce Diane L Pierce 9/24/10 (Signature) (Date)	Branch/Mail Code: / Phone Number: (919) 541-2708 Fax Number: 919-541-0496
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Contractor Acknowledgement of Receipt and Approval of Workplan (Signature and Title)	Date

WA 1-58

STATEMENT OF WORK

THE IMPACT OF DECONTAMINATION TECHNOLOGIES (ETHYLENE OXIDE) ON MATERIALS AND EQUIPMENT

OMIS DCMD 3.26C
(APPCD ON-SITE CONTRACT EP-C-09-027)

U.S. ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HOMELAND SECURITY RESEARCH CENTER
DECONTAMINATION AND CONSEQUENCE MANAGEMENT DIVISION

TABLE OF CONTENTS

I. TITLE

The Impact of Decontamination Technologies (Ethylene Oxide) on Materials and Equipment

II. PERIOD OF PERFORMANCE

The period of performance for the work under this work assignment shall be 9/27/10 – 3/31/11.

III. SUMMARY OF OBJECTIVES

This work shall determine the impact of fumigation with ethylene oxide at sporicidal conditions on electronic equipment.

IV. RELEVANCE

Fumigation with ethylene oxide for the decontamination of certain materials and equipment contaminated with anthrax spores has been suggested as a safe alternative to more harsh fumigants such as chlorine dioxide or hydrogen peroxide. Unlike hydrogen peroxide and chlorine dioxide, ethylene oxide is not an oxidizing agent and kills organisms through alkylation. Information on the compatibility of materials and equipment with typical ethylene oxide fumigation conditions effective for anthrax spores has not been determined in a systematic, reproducible way. Future guidance on selection and operation of decontamination technologies is dependent upon such information.

V. BACKGROUND

Under Homeland Security Presidential Directive (HSPD) 10, the U.S. Department of Homeland Security (DHS) is tasked to coordinate with other appropriate Federal departments and agencies, to develop comprehensive plans which, "provide for seamless, coordinated Federal, state, local, and international responses to a biological attack." As part of these plans, the U.S. Environmental Protection Agency (EPA), in a coordinated effort with DHS, is responsible for "developing strategies, guidelines, and plans for decontamination of persons, equipment, and facilities" to mitigate the risks of contamination following a biological weapons attack.

DHS is committed to using cutting-edge technologies and scientific talent in its quest to make America safer. The DHS Science and Technology Directorate (S&T) is tasked with researching and organizing the scientific, engineering, and technological resources of the United States and leveraging these existing resources into technological tools to help protect the homeland.

EPA's National Homeland Security Research Center (NHSRC) provides expertise and products that can be widely used to prevent, prepare for, and recover from public health and environmental emergencies arising from terrorist threats and incidents. NHSRC's Decontamination and Consequence Management Division (DCMD)'s decontamination research program's goal is to provides expertise and guidance on the selection and implementation of decontamination methods and provide the scientific basis for a significant reduction in the time and cost of decontamination events.

Past field experience and recent laboratory investigation have shown the effectiveness of several decontamination technologies for use against anthrax spores and other biological agents. The effectiveness of the technologies varies significantly as a function of operating conditions and challenge conditions (e.g., materials intended to be decontaminated). The use of chlorine dioxide (ClO_2) gas, fumigant hydrogen peroxide (H_2O_2), and methyl bromide has been shown to be effective in the field and laboratory when used in the appropriate circumstances. In addition to efficacy, the development of the remediation strategy also includes consideration of the ability to achieve effective conditions (e.g., fumigant concentration) within the application scenario and the impact of the decontamination process on materials and equipment.

In 2007, EPA and DHS partnered with the National Geo-spatial Intelligence Agency (NGA) to assess the impact of chlorine dioxide gas on electronic equipment. In 2008, the partnership was continued to assess the impact of two hydrogen peroxide technologies. It is intended that a new IA will be established with DHS to complete the assessment of the impact of ethylene oxide fumigation on electronic equipment. These past efforts accessed the special analyses required for this effort by LGS/Alcatel-Lucent. In order to provide for a comparable assessment to the past effort, it is critical that the analysis of

the equipment be done utilizing the priority methods and analysis as developed and performed under the previous partnerships. It is anticipated that another equipment analysis contract (EAC) will be completed to provide material analysis capabilities.

VI. SCOPE

The purpose of this study is to determine the impact of ethylene oxide fumigation on relevant materials and equipment at decontamination conditions required for sporicidal kill in public facilities. This Statement of Work (SOW) covers the implementation of the treatment test matrix, the protocol for initial diagnostics, the comprehensive analysis of the treated equipment, and the reporting of the findings.

VII. TECHNICAL APPROACH

The contractor, upon approval from the EPA WAM, shall procure all test equipment and materials to be included in the test sets. The test equipment and materials are considered expendable items in this project. The contractor shall conduct pre-screening and documentation of all test equipment and materials prior to exposure to the fumigation conditions in accordance with the approved Quality Assurance Project Plan (QAPP). The contractor shall set-up the experimental system necessary to complete the fumigation testing. The system shall allow for temperature, RH and ethylene oxide concentration controlled exposures for up to 48 hrs. The equipment shall be exposed to ethylene oxide by the contractor according to the finalized test matrix. The contractor shall then re-run the diagnostic protocol on fumigated computers and assess the impact on the other equipment and materials per the protocols. The contractor shall provide all data to the EPA WAM within one week following the fumigation test and within one week after completing diagnostic analysis on each computer system. For Category 4 equipment, the contractor shall participate with the U.S. EPA in discussions with the EAC to decide which computer systems shall be deemed most appropriate for in-depth analysis. After a decision by the EPA WAM, the contractor shall ship the appropriate equipment to the EAC per the shipping protocol in the approved QAPP. All material and equipment shall be evaluated per the appropriate protocol (as documented in the approved QAPP) monthly for a period of 1 year following the fumigation date.

VIII. AFFORDABILITY

This effort is labor intensive, which is where the bulk of the funding is required. The contractor shall procure all test materials/equipment. The ethylene oxide chamber will be provided by the EPA and is not included as part of this WA.

IX. TECHNICAL RISK

The technical risk involved in this project is minimal. The ultimate goal in Task 1 is to determine the effect of the ethylene oxide fumigation on electronic equipment. The null and alternative hypotheses are expected to be easily determined and verified.

X. FACILITIES AND MATERIALS

All experimental efforts shall be performed by the contractor at the U.S. EPA's Decontamination Technologies Research Laboratory (DTRL) located on the U.S. EPA campus in Research Triangle Park, NC. The ethylene oxide chamber will be provided by the EPA and is not included as part of this WA.

XI. TASKS

The work to complete the tasks listed below shall be conducted in the NHSRC/DCMD's Decontamination Technologies Research Laboratories (DTRL) located on EPA's Research Triangle Park, NC campus. The deliverable dates and availability of vendor-supplied equipment shall be used by the contractor work assignment leader (WAL), in consultation with the EPA WAM, to determine the testing schedules.

The assessment of the impacts on three categories of items separated according to the analysis requirements shall be completed. The first category of materials (Category 2; there is no Category 1 for this SOW, but the numbering is maintained from previous efforts for consistency) includes materials that will be of typically low surface area within a building, but their functionality may be impacted by the fumigant or fumigation process. Analysis of the items in this category include visual inspection, surface analysis on selected samples (e.g., SEM), and standard methods for such materials as used within buildings (e.g., conductivity testing). The third category of materials (Category 3) includes small, personal

electronic equipment and electrical circuits. The analysis shall be limited to functionality testing and visual inspection. The fourth category of materials (Category 4) includes computers and monitors. The primary focus for Category 4 materials is on the impact of the fumigant on the functionality of the equipment (material compatibility). The analysis for Category 4 equipment shall include specialized testing of such sensitive electronic equipment for impact and lifetime analysis performed by the EAC through an independent EPA vehicle.

The following tasks are defined as part of this work assignment:

Task 1 – Characterization of Ethylene Oxide System
The ethylene oxide generation system that will be used in this work assignment is manufactured by Andersen Products of Haw River, NC. This system has been used as a sterilization unit in the medical industry for more than 50 years. The unit utilizes a pre-loaded cartridge to provide a sustained release of ethylene oxide over a given period of time. The ethylene oxide generation rate is something that the manufacturer may or may not provide to the EPA. As part of this work assignment the contractor shall determine the ethylene oxide generation rate of the system as a function of time. The relative humidity and temperature of the system shall also be monitored during the ethylene oxide generation step. This Task shall also include monitoring the ethylene oxide concentration during the aeration phase.

Task 2 – Material Demand and Efficacy Testing
After characterization results have been obtained in Task 1, the WAM in consultation with the Contractor WAL shall determine whether efficacy testing is required to determine if the Andersen system achieves sporicidal conditions during a test cycle. This task may involve material demand measurements where representative materials are exposed to ethylene oxide to determine if the ethylene oxide absorbs or reacts with the material thus reducing the concentration in the chamber. Efficacy testing in this project would utilize *Bacillus atropheus* or another appropriate surrogate for *Bacillus anthracis.* If the WAM decides to pursue material demand and efficacy testing the contractor shall prepare and submit a QAPP/Test Plan prior to any work being done, this is listed as Task 3. No data collection will begin until the QAPP is approved.

Task 3 – Development of the QAPP/Test Plan
The contractor shall write a Test/QA Plan for the project which shall include the material demand and efficacy testing if this route is chosen by the WAM. The Test plan shall include the material compatibility testing (exposure and analysis) for Category 2, 3, and 4 materials for testing with ethylene oxide. The contractor shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this work assignment (see Attachment #1 to the SOW) and the NHSRC QA requirement as defined in Attachment #2 to the SOW. The QAPP must be approved prior to the start of any work. Additional information related to QA requirements can be found at: http://www.epa.gov/quality/qs-docs/r5-final.pdf.

Task 4 - Determination of Test Equipment, Materials and Test Matrix
NHSRC is interested in the effects of decontamination processes for biological agents on electronic equipment. The fumigant of interest for this effort is ethylene oxide. The test materials and equipment for this effort shall include those items listed in Table 1 for Category 2 materials and Table 2 for Category 3 materials. Category 4 Equipment shall include desktop computers and monitors consistent with those used in previous material compatibility projects, these items are a Dell OptiPlex 745 Desktop Computer, a Dell 15 inch Flat Panel Monitor (see Appendix A for specifications), a USB keyboard and mouse, and a computer and monitor power cords and connecting analog video cable (SVGA). If the model 745 computer is no longer available an equivalent model shall be selected by the EPA WAM. All materials and equipment required for this testing shall be procured by the contractor as expendable test materials. Additional materials and equipment may be added to this list by the EPA WAM provided that it is within the available level of effort for the project or additional funding is provided via amendment of this work assignment. Additionally, a standard set of coupons to be fumigated with the computers shall be provided to the contractor by the EPA WAM. All materials and equipment shall be fumigated in triplicate at each

test condition. The contractor shall assume that 8 computer systems shall be procured to complete this project.

Table 1: Category 2 Materials

Material	Description	Supplier/ Manufacturer	Part Number	Coupon/ Sample Size
Type 3003 Aluminum	Textured 0.0625 inch thick sheet	McMaster Carr	88685K12	2" x 2", 3 pieces
Alloy 101 Copper	0.064" thick polished electrical grade, 99.99% pure	McMaster Carr	3350K19	2" x 2", 3 pieces
Low Carbon Steel	Un-milled 0.0625" thick	McMaster Carr	6615K29	1 ½" x 2" , 3 pieces
Type 316 Stainless Steel	0.0625" thick 2B finish	McMaster Carr	9090K11	2" x 2" , 3 pieces
Type 304 Stainless Steel	0.0625" thick #3 finish	McMaster Carr	9085K11	2" x 2" , 3 pieces
Type 410 Stainless Steel	0.0625 " thick	McMaster Carr	9524K62	2" x 2" , 3 pieces
Type 430 Stainless Steel	0.012" thick unpolished	McMaster Carr	8457K43	1" x 2" , 3 pieces
Type 309 Stainless Steel	0.0625" thick	McMaster Carr	9205K151	1 ½" x 2" , 3 pieces
DSL Line Conditioner	Phone and DSL connectors embedded within	McMaster Carr	1522T23	1 piece
Incandescent Light	With electrical switch	McMaster Carr	1627K48	1 piece
Steel Outlet/Switch Box	2" x 3 " x 1 ½ "	McMaster Carr	71695K81	1 piece
Silicone Caulk	Applied to switch box to test sealing capacity	McMaster Carr	7582T15	1" x 1"
Type 3003 Aluminum	Textured 0.0625 inch thick sheet	McMaster Carr	88685K12	2" x 2", 3 pieces
Yellow SJTO 300 VAC Service cord	16/3 AWG, .33" OD	McMaster Carr	8169K39	3 pieces
Smoke Detector	Battery-powered Ionization sensor with battery	First Alert	SA304	1 piece
Laser printed paper	Stack of 15 pages (first 15 pages of this QAPP)	RTO-E340-PS HP Color LaserJet	NA	8 ½" x 11"
Ink jet colored paper	Stack of 15 pages (test page used in previous work)	HP DeskJet 932C	NA	8 ½" x 11"
Color Photograph	4" x 6" Kodak processing	Walgreens	NA	4" x 6", 3 pieces
Static Intercept bags	20" x 24" x 0.003" bags	Dasal Technical products	NA	1 piece
ABS plastic	0.125" thick	McMaster Carr	8586K101	1½" x 2", 3 pieces
High density polyethylene plastic film	4 mil HDPE stretched across PVC tube	McMaster Carr	8552K81	2" x 4", 3 pieces
Low density polyethylene	4 mil LDPE stretched across PVC tube	McMaster Carr	8553K814	2" x 4", 3 pieces

Material	Description	Supplier/ Manufacturer	Part Number	Coupon/ Sample Size
plastic film				
Duct tape	2" wide Premium Duty, Fed. Spec. PPP-T-60E, Type IV, Class I. Used to seal plastic films onto PVC tube	McMaster Carr	7612A7	12" long circumference, 6 pieces
PVC plastic	2" x 4" rectangular tube, 0.098" wall	McMaster Carr	85095K95	1" length, 3 pieces

Table 2: Category 3 Materials and Equipment

Equipment	Description	Manufacturer	Model Number	Sample Size
Personal Digital Assistant (PDA)	Handheld	Palm	Z22	1 piece
Cell Phone	Pay as you go Super thin flip super phonic ring tones full color screen	Virgin (Kyocera)	Marbl	1 piece
Fax/Phone/ Copier Machine	Plain-paper fax and copier with 10-page auto document feeder and up to 50-sheet paper capacity. 512KB memory stores up to 25 pages for out-of-paper fax reception	Brother	Fax 575	1 piece
Data CD	Software CD	Snap!	01-0170-026-000	1 piece
Data DVD	Standard 21331 DVD Video	Warner Brothers	Harry Potter And the Sorcerer's Stone DVD	1 piece

The contractor shall provide technical support to the EPA WAM in the final decision on the material/equipment to be included based upon an understanding of the objectives of the study and the physical properties/behavior of the fumigant.

The test matrix is shown in Table 3. In Test 2, computer system test set will be fumigated individually. Thus, three fumigation cycles (or runs) will be required to complete Test 2 (fumigate all 3 computer system test sets). The exposure conditions will be determined through scoping tests with the ethylene oxide system. The conditions will be chosen and documented in an amendment to the QAPP. Because of the explosive nature of ethylene oxide all systems will be fumigated in the off state.

Table 3A: Test Matrix for Category 2 and 3 Materials/Equipment

Test Condition	Equipment Power State During Fumigation	Treatment Conditions
1	Off	Ethylene Oxide: RH, T, and other conditions to be determined
2	Off	No Ethylene Oxide: same time, humidity and temperature in Test 1

Table 3B: Test Matrix for Category 4 Materials/Equipment

Test Condition	Equipment Power State During Fumigation	Treatment Conditions
1	Off	Ethylene Oxide: RH, T, and other conditions to be determined
2	Off	Ethylene Oxide: RH, T, and other conditions to be determined
3	Off	Ethylene Oxide: RH, T, and other conditions to be determined
4	Off	No Ethylene Oxide: same time, humidity and temperature in Tests 1-3
5	ON and Idle	Standard fumigation conditions (3000 ppmv ClO_2, 75 % RH, 75 °F, 3 hrs)

Task 5 – Conducting the Compatibility Testing

The contractor shall conduct the testing described in the QAPP that will be developed in Task 3. This shall include running diagnostic testing on all equipment, including running the PC Doctor protocol on all computer systems. The PC Doctor protocol shall be provided by the EPA WAM. Digital photographs and documentation of the appearance or relevant properties, consistent with those defined in the QAPP, shall be made prior to exposure of the equipment/materials to the test conditions. The contractor shall assemble the necessary fumigation equipment to conduct the treatments. The equipment/materials shall be treated in accordance with the finalized test matrix to be included in the QAPP. After exposure, the assessment of the impact of the fumigation on the equipment/materials shall be performed. The assessment shall include complete documentation and digital photographs of all items. For computer systems, the PC Doctor diagnostic protocol shall be run post-exposure to the fumigation conditions. All assessments, including PC Doctor, shall be made monthly for up to one year following the fumigation event.

Residual off-gasing from the materials and equipment shall also be investigated after exposure to ethylene oxide. The contractor shall determine the appropriate methods and test matrix for the assessment of off-gasing. This shall be approved by the EPA WAM in the review/approval of the QAPP. As an example, after each of the three fumigation cycles comprising Test 2, off-gassing of ethylene oxide shall be determined by using an appropriate monitoring method. Off-gasing for relevant materials (e.g., gaskets) and equipment (e.g., cellphones) shall also be completed. The list of equipment/materials to be included in the off-gasing analysis shall be proposed to the EPA WAM by the contractor.

The contractor shall coordinate shipment of Category 4 equipment for analysis by the EAC according the packaging and shipping method to be defined in the QAPP. After each fumigation cycle, all coupons provided by the EAC in the computer systems shall be sent by the contractor to the EAC for subsequent analysis.

The execution of the test matrix requires that the experimental system be set-up in which the equipment and materials can be exposed to ethylene oxide at controllable conditions (temperature, RH, and concentration). The system that the EPA is procuring was developed by Andersen Products. The system includes the chamber and aeration system. The contractor may be responsible for ensuring compliance with all necessary safety requirements which may include connecting the chamber to an exhaust duct. Data from shakedown runs shall be presented to the

EPA WAM prior to commencement of the test matrix in order to prove adequate controls, as defined per the data quality objectives and indicators specified in the approved QAPP.

The contractor shall develop the health and safety research protocol (HSRP) for this work and obtain approval from the contractor and U.S. EPA health and safety officers prior to commencement of any studies with ethylene oxide.

Task 6 – Reporting

All data collected per the QAPP shall be submitted to the EPA WAM within one week after the completion of the analysis. Submission shall be via posting on the NHSRC share drive. Additionally, data on the Category 4 equipment shall be submitted directly to the EAC with a carbon copy to the EPA WAM. This shall include copies of log books and all relevant electronic files. All data shall be QA/QC'd before being sent to the EAC.

The contractor shall submit a draft report on the compilation of results from the efficacy testing and material and equipment compatibility testing (Category 2 and 3 only) by 3/31/11. The report shall include photographic and graphical documentation, where appropriate, to support the findings. The report shall be provided in both hardcopy and electronic (MS Word) format. This report will not include the results from Category 4 items.

XII. DELIVERABLE SCHEDULE

- On a monthly basis for the duration of the project, the contractor shall submit, in electronic format, progress reports summarizing technical progress (including estimated percent of project completed), problems encountered, quarterly and cumulative financial expenditures and cost and schedule variance.
- A draft report shall be delivered to the EPA WAM by 3/31/11.

Table 4: Deliverable Schedule

Deliverable	Date
Draft QAPP/Test Plan	1 month after Task 1 ends
Final QAPP/Test Plan	2 weeks after reviews are returned to contractor
Data summaries	On-going
Draft Report	3/31/11

XIII. REPORTING REQUIREMENTS

- The Contractor shall prepare Quality Control data reports of all facility-specific data. Each Quality Control report shall be in a format suitable for EPA/NHSRC publication and shall discuss how well various measurements described in the QA plan were met.
- The monthly invoice reports for this work assignment shall provide a detailed description of any equipment or expendables that have been purchased by the contractor for use on the projects discussed herein.
- In lieu of a final technical report, journal papers within each task may be submitted at the discretion of the EPA WAM. The papers shall be authored or co-authored by the EPA WAM, at the discretion of the WAM. To serve in lieu of the final report, the journal articles must contain all of the relevant information that would have appeared in the final report.
- All products developed under this SOW (e.g., the above mentioned technical report) must conform to the requirements of EPA's Handbook for Preparing Office of Research and Development Reports (EPA/800/K-95/002). Substantive portions of this handbook can be found at www.epa.gov/nhsrc under the policy and guidance tab.

NHSRC QUALITY ASSURANCE REQUIREMENTS FORM
Attachment 1 to the Statement of Work

I GENERAL INFORMATION

Title:	The Impact of Decontamintion Technologies (Ethylene Oxide) on Materials and Equipment	
Description:	Ethylene Oxide	
Project ID:	DCMD 3.26C	
Status:	Original	
Number Ammended:		
QA Category:	III	
Action Type:	Extramural	
Peer Review Category:		
Security Classification:	Unclassified	
Project Type:	Applied Research	
QAPP Status 1:	Not Delivered	
Vehicle Status:	Existing Vehicle	
Vehicle Type:	Vehicle Number:	EP-C-09-027
	Work Assignment Number:	TBD
	Delivery/Task Order Number:	TBD
	Modification Number:	TBD
	Other:	

*If you are processing an **IAG** or **CRADA**, the responsibility for QA must be negotiated within the agreement. The TLPs in consultation with the QAMs in the various organizations must agree on, and document, which organization will take the lead for QA, the names of the QAM and TLP from each organization, and the QA requirements that will be adhered to during the agreement. Include this info in the IAG/CRADA package.*

II SCOPE OF WORK

Yes — Does the Statement of Work contain the appropriate QA language?

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action. The contractor shall prepare a QAPP in accordance with the R-2 and R-5 and/or the attachments provided with the SOW. The QAPP must be approved prior to the start of any work. Additional information related to QA requirements can be found at http://www.epa.gov/quality/qs-docs/r5-final.pdf

Yes — Does this extramural action involve the collection, generation, use, and/or reporting of environmental data; the design, construction, and operation of environmental technologies; or development of software, models, or methods?
(If "No" then skip to Section IV, and sign the form.)

No — Will the SOW or any subsequent work assignments or task orders involve any cross-organizational efforts within EPA?

No — Has a QAPP already been approved for the activities specified in the SOW?

Is an applicable QAPP in the process of being prepared, revised, or approved by EPA personnel for future use

N/A

by the contractor? (QA approval must be obtained before the contractor can start work.)

III QA DOCUMENTATION OPTIONS

All documentation specified under "Other" must be defined in the NHSRC Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For all items checked below, there must be adequate information in the SOW (or its appendices) for the offeror to develop this documentation. Where applicable, reference a specific section of the SOW. *(R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01). Copies of these documents are available at http://www.epa.gov/quality/qa_docs.html.)*

After Award Documentation

Not Applicable	Documentation of an organization's Quality System. QMP developed in accordance with:
Not Applicable	Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Developed in accordance with:
Other	Documentation of the application of QA and QC activities to applicable project(s). Developed in accordance with:
	Explain: QA documentation can be developed in accordance with R2 and R5 or the developer can defer to attachment #1 (QAPP requirements for APPLIED RESEARCH) and #2 (Quality System Specifications for Extramural Actions)
n/a	Programmatic QA Project Plan with supplements for each specific project, developed in accordance with:
Not Applicable	Existing documentation of the application of QA and QC activities will be used:

IV SIGNATURE BLOCK

The signatures below verify that the Statement of Work (SOW) has been reviewed to ascertain the necessary QA and QC activities required to comply with EPA Order 5360.1 A2, that the COR understands these requirements, and that the COR will ensure that the quality requirements indicated on the previous pages of this form are incorporated into all associated SOWs. *(Sign/date below, obtain a concurrence signature from the QA Staff, and submit the form along with the other extramural action documentation.)*

Signature on file		Ramona Sherman SEP 15	
Shannon Serre NHSRC-IO Technical Lead Person	09/15/2010 Date	Ramona Sherman NHSRC-IO QA Staff Member	09/15/2010 Date

QAPP REQUIREMENTS FOR APPLIED RESEARCH PROJECTS

(from Appendix B of the NHSRC QMP)

An applied research project is a study to demonstrate the performance of technologies under defined conditions. These studies are often pilot- or field-scale. The following requirements should be addressed as applicable.

SECTION 0.0, APPROVAL BY PROJECT PARTICIPANTS

The EPA Technical Lead Person (TLP) shall be responsible for obtaining signatures of appropriate project participants on the signature page of the QA plan, documenting agreement to project objectives and the approach for evaluating these objectives.

A distribution list shall be provided to facilitate the distribution of the most recent current version of the QAPP to all the principal project participants.

SECTION 1.0, PROJECT DESCRIPTION AND OBJECTIVES

1.1 The purpose of study shall be clearly stated.

1.2 The process, site, facility, and/or environmental system to be tested shall be described.

1.3 Project objectives shall be clearly stated and identified as primary or non-primary.

SECTION 2.0, PROJECT ORGANIZATION

2.1 Key points of contact for each organization involved in the project shall be identified.

2.2 All QA Managers and their relationship in the organizations (*i.e.*, location within each organization) shall be identified with evidence that the QA Manager is independent of project management.

2.3 Responsibilities of all other project participants and their relationship to other project participants shall be identified, meaning that organizations responsible for planning, coordination, sample collection, sample custody, measurements (*i.e.*, analytical, physical, and process), data reduction, data validation, and report preparation shall be clearly identified.

SECTION 3.0, EXPERIMENTAL APPROACH

3.1 The general approach and the test conditions for each experimental phase shall be provided. The statistical methods that will be used to evaluate the data (*i.e.*, ANOVA, or summary statistics) should be identified.

(NOTE: As deemed appropriate to the project by the TLP, the information requested in Sections 3.2, 3.3, and 3.4 may be presented here or in Section 4; the information requested in Sections 3.5 may be presented here or in Section 5; and the information requested in Sections 3.6 may be presented here or in Section 7.)

3.2 The sampling strategy shall be included and evidence must be presented to demonstrate that the strategy is appropriate for meeting primary project objectives, *i.e.*, a description of the statistical method or scientific rationale used to select sample sites and number of samples shall be provided.

3.3 Sampling/monitoring points for all measurements (*i.e.*, including locations and access points) shall be identified.

3.4 The frequency of sampling/monitoring events, as well as the numbers for each sample type and/or location shall be provided, including QC and reserve samples.

3.5 All measurements (*i.e.*, analytical [chemical, microbiological, assays], physical, and process) shall be identified for each sample type or process, and project-specific target analytes shall be listed and classified as critical or noncritical in the QAPP.

3.6 The planned approach (statistical and/or non-statistical) for evaluating project objectives shall be included.

SECTION 4.0, SAMPLING PROCEDURES

4.1 Whenever applicable, the method used to establish steady-state conditions shall be described.

4.2 Known site_specific factors that may affect sampling/monitoring procedures shall be described.

4.3 Any site preparation needed prior to sampling/monitoring shall be described.

4.4 Each sampling/monitoring procedure to be used shall be discussed or referenced. If compositing or splitting samples, those procedures shall be described.

4.5 For samples requiring a split sample for either QA/QC purposes or for shipment to a different laboratory, the QAPP shall identify who is responsible for splitting samples, and where the splitting is performed (*e.g.*, field versus lab).

4.6 If sampling/monitoring equipment is used to collect critical measurement data (*i.e.*, used to calculate the final concentration of a critical parameter), the QAPP shall describe how the sampling equipment is calibrated, the frequency at which it is calibrated, and the acceptance criteria for calibration or calibration verification, as appropriate.

4.7 If sampling/monitoring equipment is used to collect critical measurement data, the QAPP shall describe how cross-contamination between samples is avoided.

4.8 The QAPP shall include a discussion of the procedures to be used to assure that representative samples are collected.

4.9 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.

4.10 Containers used for sample collection, transport, and storage for each sample type shall be described.

4.11 Describe how samples are uniquely identified.

4.12 Sample preservation methods (*e.g.*, refrigeration, acidification, *etc.*), including specific reagents, equipment, and supplies required for sample preservation shall be described.

4.13 Holding time requirements shall be noted.

4.14 Procedures for packing and shipping samples shall be described.

4.15 Procedures to maintain chain_of_custody (*e.g.*, custody seals, records) during transfer from the field to the laboratory, in the laboratory, and among contractors and subcontractors shall be described to ensure that sample integrity is maintained.

4.16 Sample archival requirements for each relevant organization shall be provided.

SECTION 5.0, TESTING AND MEASUREMENT PROTOCOLS

5.1 Each measurement method to be used shall be described in detail or referenced. Modifications to EPA_approved or similarly validated methods shall be specified.

5.2 For unproven methods, verification data applicable to expected matrices shall be included in the QAPP meaning the QAPP shall provide evidence that the proposed method is capable of achieving the desired performance.

5.3 For measurements which require a calibrated system, the QAPP shall include specific calibration procedures applicable to each project target analyte, and the procedures for verifying both initial and continuing calibrations (including frequency and acceptance criteria, and corrective actions to be performed if acceptance criteria are not met).

SECTION 6.0, QA/QC CHECKS

6.1 At a minimum, the QAPP shall include quantitative acceptance criteria for QA objectives associated with accuracy, precision, detection limits, and completeness for critical measurements (process, physical, and analytical, as applicable) for each matrix.

6.2 Any additional project-specific QA objectives shall be presented, including acceptance criteria. This includes items such as mass balance requirements.

6.3 The specific procedures used to assess all identified QA objectives shall be fully described.

6.4 The QAPP shall list and define all other QC checks and/or procedures (*e.g.*, blanks, surrogates, controls, *etc.*) used for the project, both field and laboratory.

6.5 For each specified QC check or procedure, required frequencies, associated acceptance criteria, and corrective actions to be performed if acceptance criteria are not met shall be included.

SECTION 7.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

7.1 The reporting requirements (*e.g.*, units, reporting method [wet or dry]) for each measurement and matrix shall be identified.

7.2 The deliverables expected from each organization responsible for field and laboratory activities shall be listed.

7.3 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized.

7.4 Data validation procedures specific to each organization used to ensure the reporting of accurate project data to internal and external clients shall be summarized.

7.5 Data storage requirements for each organization shall be provided.

7.6 The product document that will be prepared for the project shall be specified (*e.g.*, journal article, final report, *etc.*). The contents of this document can be referenced to a NHSRC or program-specific QMP, if appropriate.

SECTION 8.0, ASSESSMENTS

8.1 The QAPP shall identify all scheduled audits (*i.e.*, both technical system audits [TSAs] and performance evaluations [PEs]) to be performed, who will perform these audits, and who will receive the audit reports.

8.2 The QAPP shall provide procedures that are to be followed that will ensure that necessary corrective actions will be performed.

8.3 The responsible party(-ies) for implementing corrective actions shall be identified.

SECTION 9.0, REFERENCES

References shall be provided either in the body of the text as footnotes or in a separate section.

Attachment # 2

NHSRC QA
To the Statement of Work
Requirements/Definitions List

EPAs Quality System Website: http://www.epa.gov/quality
EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html
EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5360.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approve the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;
(2) an organizational chart showing the position of the QA function;
(3) delineation of the authority and responsibilities of the QA function;
(4) the background and experience of the QA personnel who will be assigned to the project; and
(5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List
Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☑ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

☑ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American

Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling" G-5M at http://www.epa.gov/quality/QS-docs/g5m-final.pdf.

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations:

COR	Contracting Officer's Representative	IAG	Interagency Agreement
NHSRC	National Homeland Security Research Center	QA	Quality Assurance
NRMRL	National Risk Management Research Laboratory	QAM	Quality Assurance Manager
QA ID	Quality Assurance Identification	QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan	SOW	Statement of Work
QS	Quality System	CRADA	Cooperative Research & Development Agreement
TLP	Technical Lead Person		

Attachment #2 to the Statement of Work
Revision 1, March 2006
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